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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/638,241	08/14/2000	Bret A. Ferree	BAF-11802/29	9686
25006	7590	02/16/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C			HO, UYEN T	
PO BOX 7021			ART UNIT	
TROY, MI 48007-7021			PAPER NUMBER	

3731

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/638,241	<b>Applicant(s)</b> FERREE, BRET A.	
	<b>Examiner</b> (Jackie) Tan-Uyen T. Ho	<b>Art Unit</b> 3731	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
     4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments and amendment with respect to have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device expanding to a size or return to memorized shaped substantially larger than the cross-sectional area of the defect must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not support the newly added limitation "allowing the device to expand to a size or return to memorized shaped substantially larger than the cross-sectional area of the defect".

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (6,224,630).

In regard to claim 12, Bao et al. disclose annular devices and methods for sealing an annular tear comprising a step of: inserting a device to an annular tear/opening/defect and occluding the tear/opening/defect by allowing the device to expand to a larger size (col. 4, lines 50-59; col. 7, line 45-59).

In regard to claim 13, Bao et al. disclose using a delivery cannula having a longitudinal moveable expulsion rod therein so that an annular device can be contained in contracted form inside the distal portion of the cannula and expelled through the tip into the tear/opening/defect.

In regard to claims 14, 15, 21 and 22, Bao et al. disclose the annular devices comprising a porous material and being made from polymers, metallic and alloys material and the device can be formed of a plug or sheet-like or a cylindrical plug with mushroom, spool-like or anvil-like configuration at end portions in order to prevent migration of the plug (col. 7, line 45 to col. 8, line 65). Additional anchoring means in forms of polymeric meshes or tines, staples (with broadest reasonable interpretation contains spike) or suture (with broadest reasonable interpretation contains wire) for anchoring the annular device in place relative to the tear/opening/defect.

In regard to claim 16, Bao et al. disclose the annular device includes material that swell by hydration such device inherently will absorb liquid as following insertion of the annular device into the tear/opening/defect and the device absorbed liquid inherently solidify in order to afford securing to the tear/opening/defect.

In regard to claim 17, Bao et al. disclose the annular device includes an elastomer (col. 16, claim 27) or a hydrogel such as poly vinyl alcohol (col. 15, claim 6).

In regard to claim 18, Bao et al. method and device occludes the defect while inherently allowing compression and distraction of the disc with respect to normal spinal movement.

Although, Bao do not disclose the device larger the defect area but suggest one end of the device enlarged in order to prevent migration of the device and better contain nuclear material. It is well known in the art to have a cover larger than a hole in order to better seal the hole. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Bao reference by having an end larger than the defect area in order to better seal the defect area.

Furthermore, it would have been obvious matter of design choice to modify the Bao et al. reference to allowing the device to expand to a size larger than the cross-sectional area of the defect since applicant has not disclosed that allowing the device to expand to a size larger than the cross-sectional area of the defect for any particular reason or to solve any stated problem and it appears that the result of the procedure of Bao et al. is equally well with the procedure allowing the device to expand to a size larger than the cross-sectional area of the defect.

Regarding claim 20, Bao et al. teach the annular device for hernia repair being self-expandable such as expandable when it is released from constraining means and the device being made from plastic, metal or alloy. Although, Bao et al. do not disclose the annular device being made from titanium, Titanium is well known metal material in the art for use to make self-expandable surgical device such as anchor, occluding implant or implant support and patch. Therefore, it would have been obvious to one

having ordinary skill in the art at the time the invention was made to make Bao et al.'s device from titanium material in order to provide the device with self-expandable characteristic as well as biocompatible.

For supporting the well-known statement, examiner provides two references that disclose using titanium to make surgical patch or occluding implant: Brown 5,824,082; Ruiz 5,976,174.

Regarding claim 23, it would have been obvious matter of design choice to anchoring the device to an adjacent vertebral body since applicant has not disclose that anchoring the device to the specific area as claimed solve any stated problem or for any particular purpose and it appears that the Bao et al.'s procedure would have the same result as the device anchored to other area as well as to the area as claimed.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
(Jackie) Tan-Uyen T. Ho  
Primary Examiner  
Art Unit 3731

February 10, 2006